# Testing the Skin Interrogation Device

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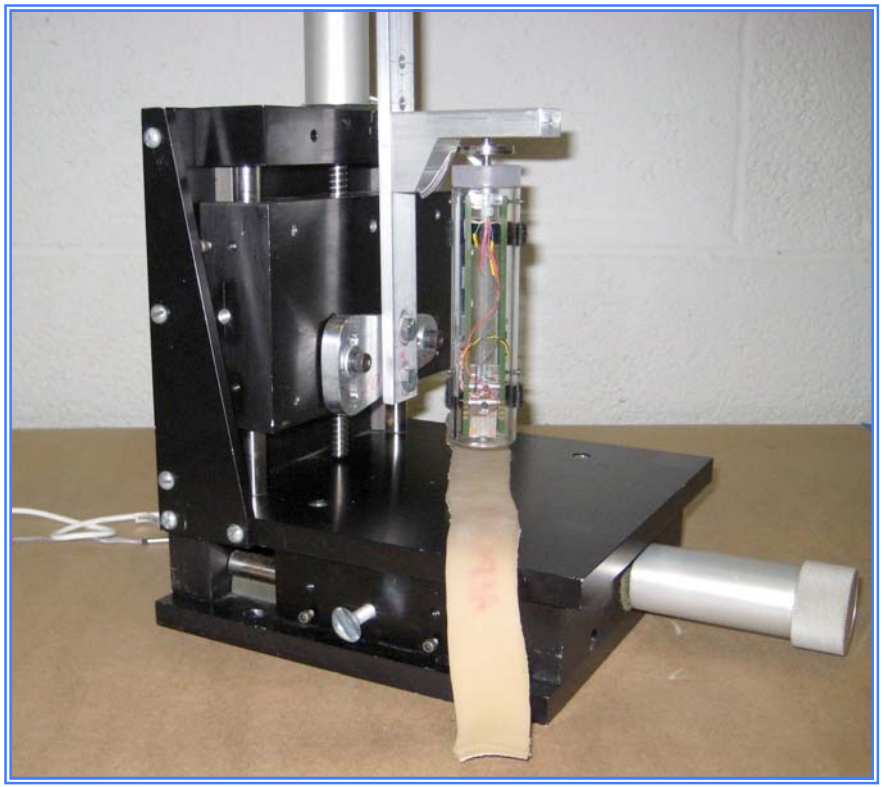
Research Project Presentation
April 9, 2008

# Outline

- Introduction
  - Significance
  - The Skin Interrogation Device
- Project Objectives
- Methods
- Results
- Conclusions



# Introduction

*My* Purpose: perform bench tests to evaluate particular aspects of the prototype “skin interrogation device”

- Device developed by CATEA and McGill University
- *Device* purpose: in-vivo measurement of the skin’s mechanical properties.

# Significance

- Detection of disease
- Evaluate effectiveness of therapeutic interventions
  (Edwards & Marks 1995, Greenleaf et al. 2003)
- Guidance for orthotic and prosthetic device recommendations

(Mak et al. 1994)

(Clip Art)

# Significance

- Predominant methods:
  - Visual inspection
  - Physical palpation
- Problems:
  - Inherently subjective and may vary with clinician experience and skill

(Mak et al. 1994, Edwards & Marks 1995, Lee et al. 2007)

- More objective alternatives seem to have limited accessibility.

# The Skin Interrogation Device

- Piezoelectric benders
- Strain gages

Design Objectives

- Quantify in-vivo mechanical properties of the skin
- Point-of-care technology
  - Low cost
  - Portable
  - Simple to use
  - Robust

# Project Objectives

Reliability: Is the performance of the device affected by the following variables?

- Ambient temperature and humidity
- Normal force
- Angle of approach

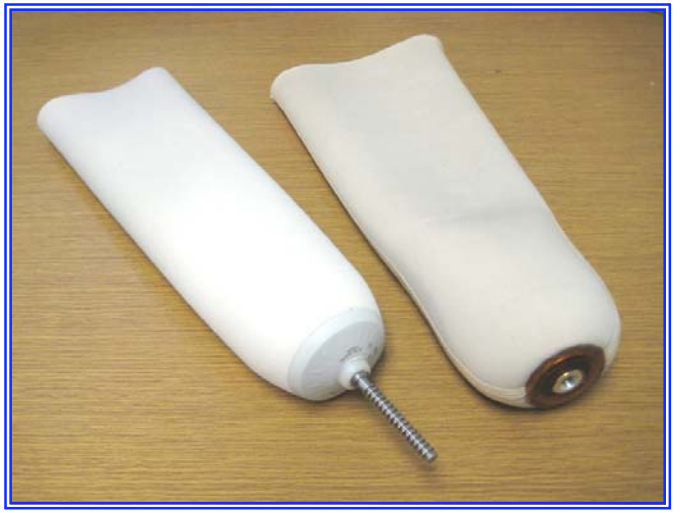
Validity:

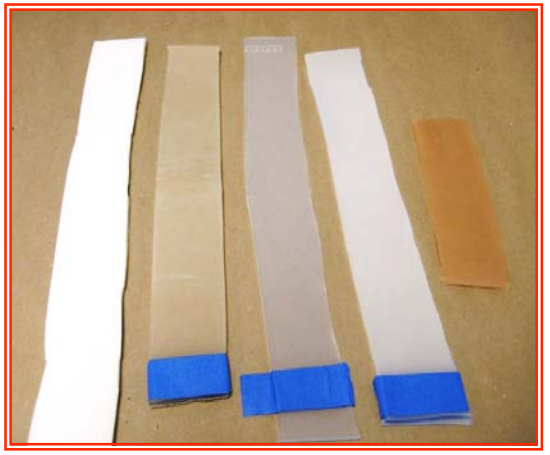
- Able to differentiate materials with different properties?
- Define the relationship: device output to known properties

# Methods: Materials

- Test material = commercially available prosthetic liners
- n = 12 different liners
- Properties known

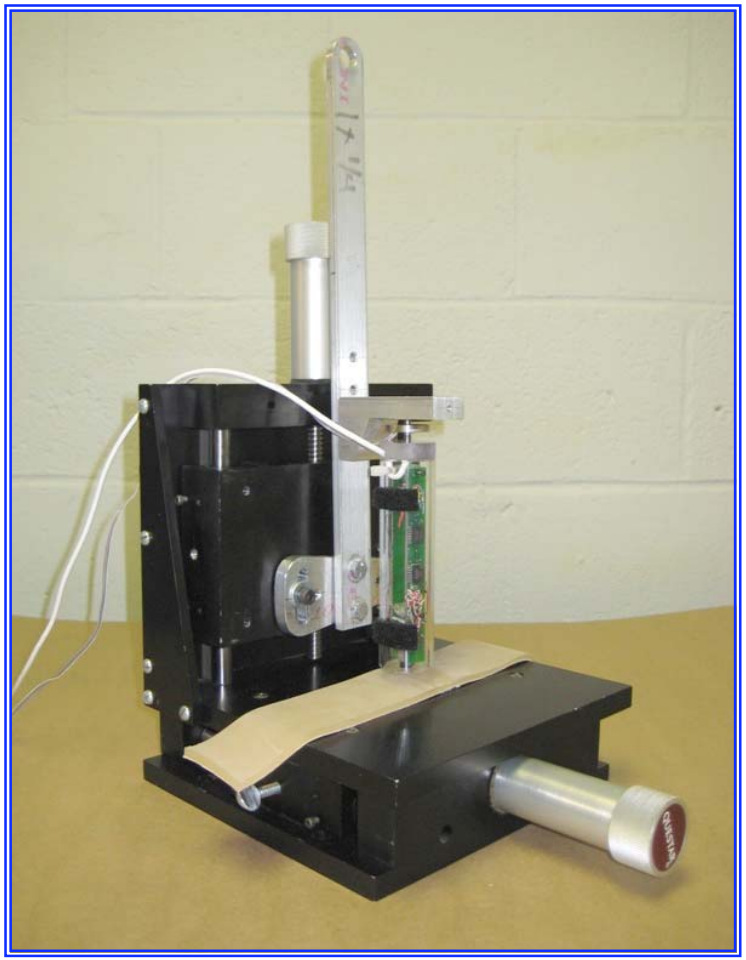
  (Sanders et al. 2004)
- Tested in Randomized order





# Methods: Set-up

- Bench-top Positioning Device
- Load Cell
- Constant loading conditions
  - Application force = 5N
  - Approach angle = vertical
- 8 trial repetitions per liner



## Data Analysis

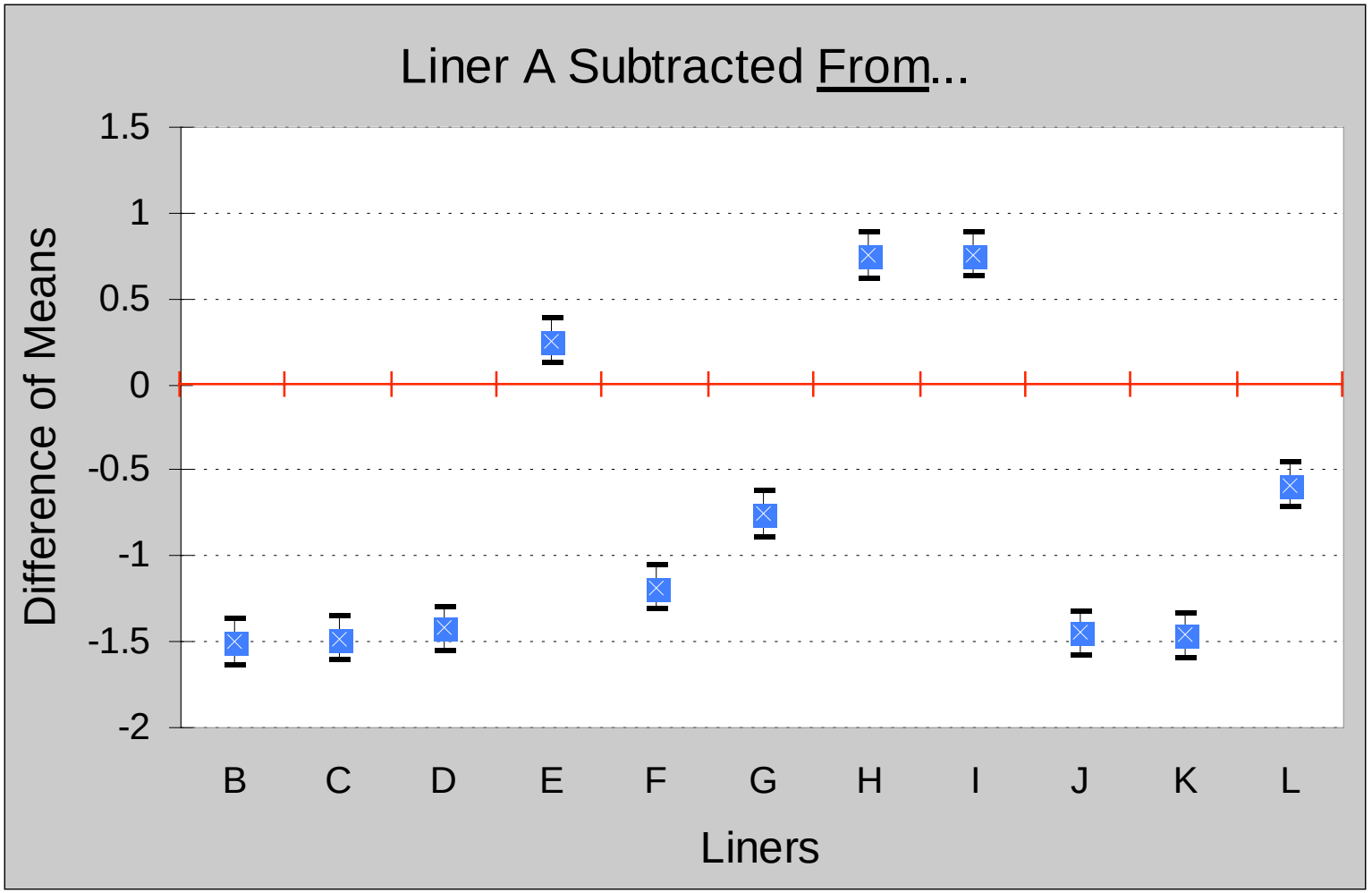
- Data Format = approximate stiffness based on strain gage voltage

## Statistics

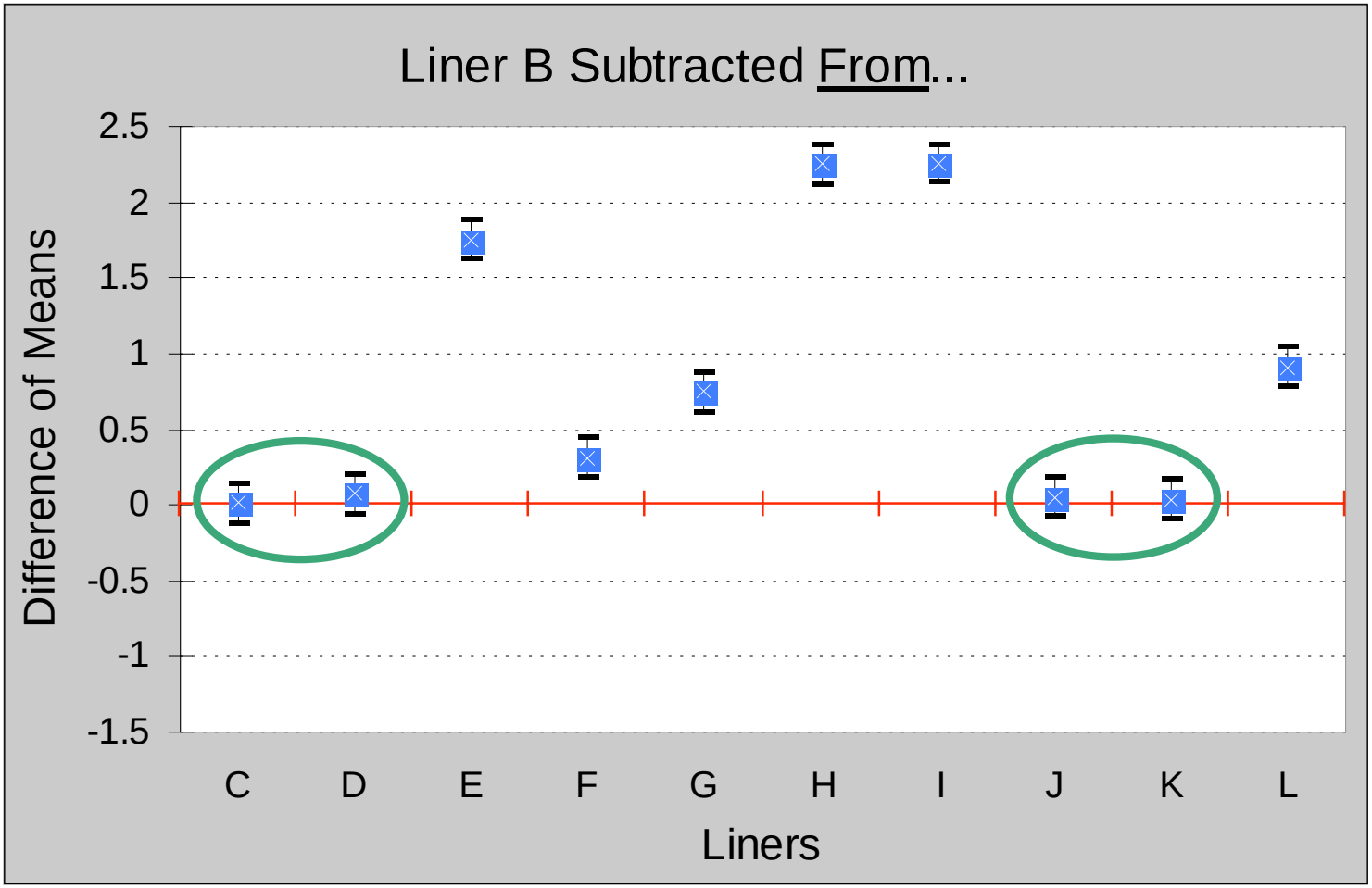
- Liner Differentiation:
  - Un-paired ANOVA ($\alpha = 0.05$)
  - Tukey's post-hoc tests (confidence intervals = 95%)
- Relationship to known properties:
  - Regression Analysis
  - Response Variable = approximate stiffness from SID
  - Explanatory Variable = reported shear stiffness

# Results: Able to differentiate materials?

- Example 1:



- Example 2:

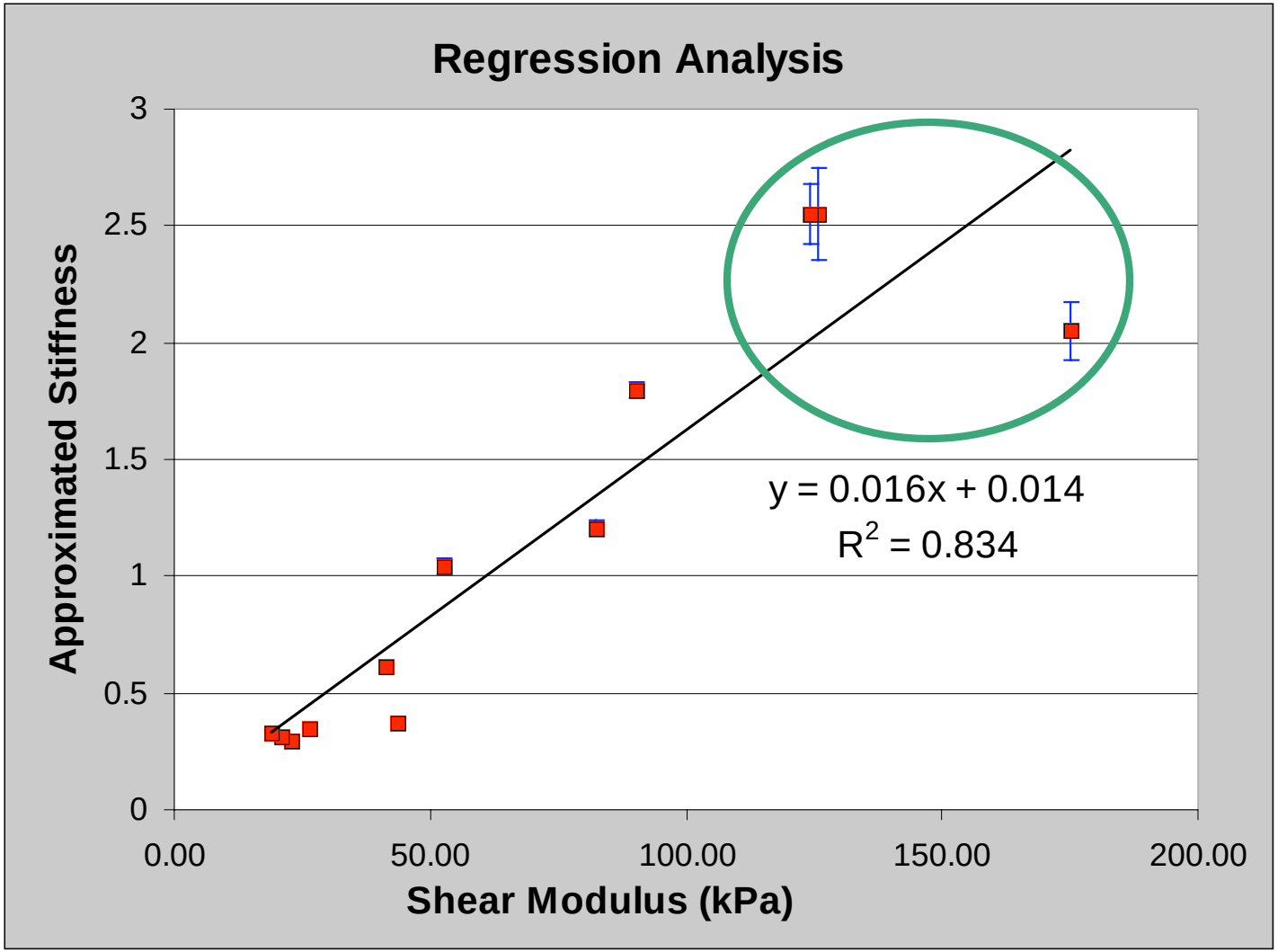



- Overall: differentiated 55 of 66 (83%) liner pairs

# Results: Able to differentiate materials?

| Changing Variable | Mean % Difference |
|---|---|
| Temperature Range (69.4° to 75.2°) | 2.21% |
| 0.8N change in Application Force | 13.58% (0.69 to 31.00) |
| 4° variation in Approach Angle | 30.52% (1.05 to 74.07) |
| Liner Comparisons | 82.45% (0.13 to 158.76) |
| Pathology Example: Scleroderma | 68% stiffer than unaffected skin (Edwards & Marks 1995) |

# Results: Relationship between device output and known properties?



# Conclusions

- Changes in the prototype's output do appear to reflect changes in stiffness properties.
- The prototype is capable of differentiating materials that have differences in these stiffness properties.

# Conclusions

- Limitations:
  - Unknown differences between my liners and those studied by Sanders et al. in 2004
  - Prosthetic Liners ≠ Skin
- Future Work:
  - Sensitivity analysis using physical models of skin morphology.
  - Human subject trials to assess validity in the clinical setting.

# References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- Sanders JE, Nicholson BS, Zachariah SG, Cassisi DV, Karchin A, Fergason JR. Testing of elastomeric liners used in limb prosthetics: classification of 15 products by mechanical performance. *J of Rehabil Res Dev* 2004;41(2):175-186.
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- Wang Q, Kong L, Sprigle S, Hayward V. Portable gage for pressure ulcer detection. Paper presented at the 28th IEEE EMBS Annual International Conference, New York, NY, August 30 – September3, 2006.

# Thank You

- CATEA
  - Dr. Sprigle
  - Jayme Caspall
  - Ricardo Lopez
  - Jonathan Jowers

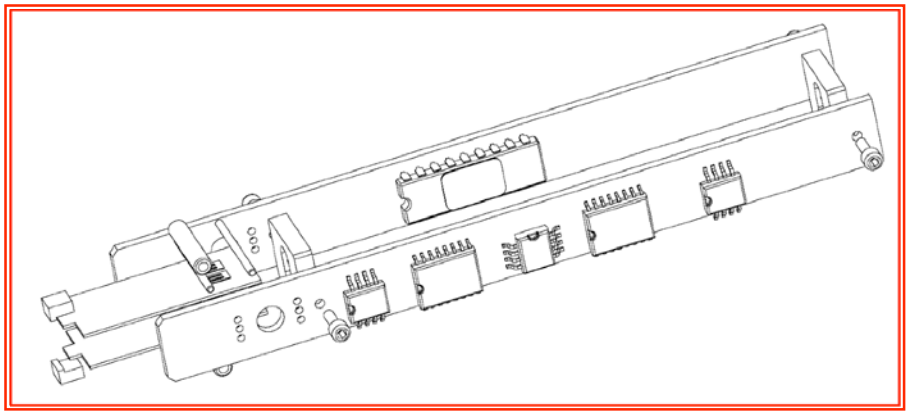
- Prosthetic Liner Providers
  - Ossur, OttoBock, OWW, Alps, Silipose, ESP

# Questions?

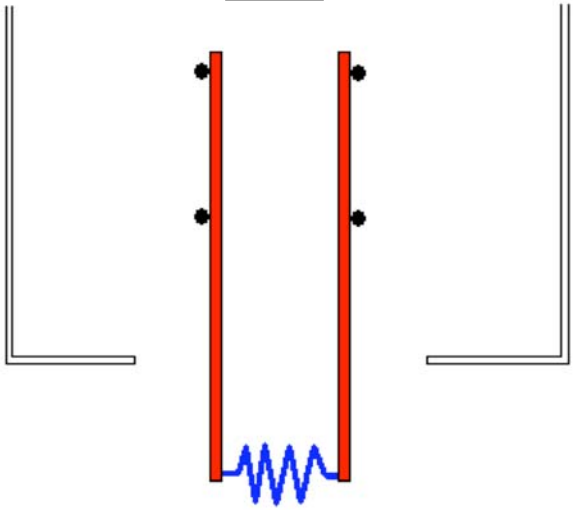
# Extra Slides

# The Skin Interrogation Device

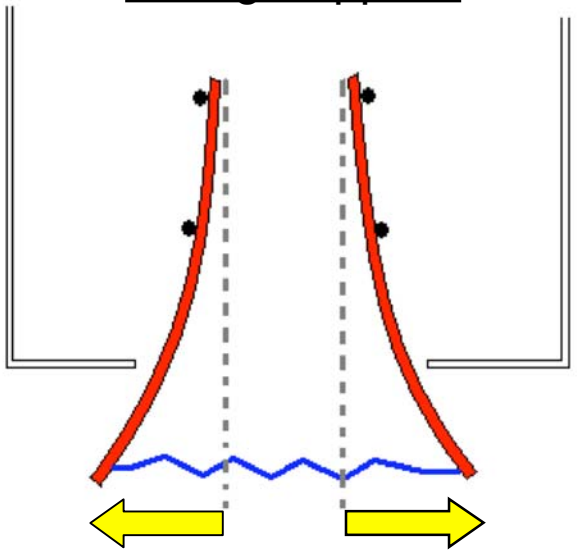
- Benders actuate to apply stress to isolated region of skin
- Strain Gages
- Load cell
- Feet with High Friction Coating
- LabView Software Interface



Rest



Voltage Applied

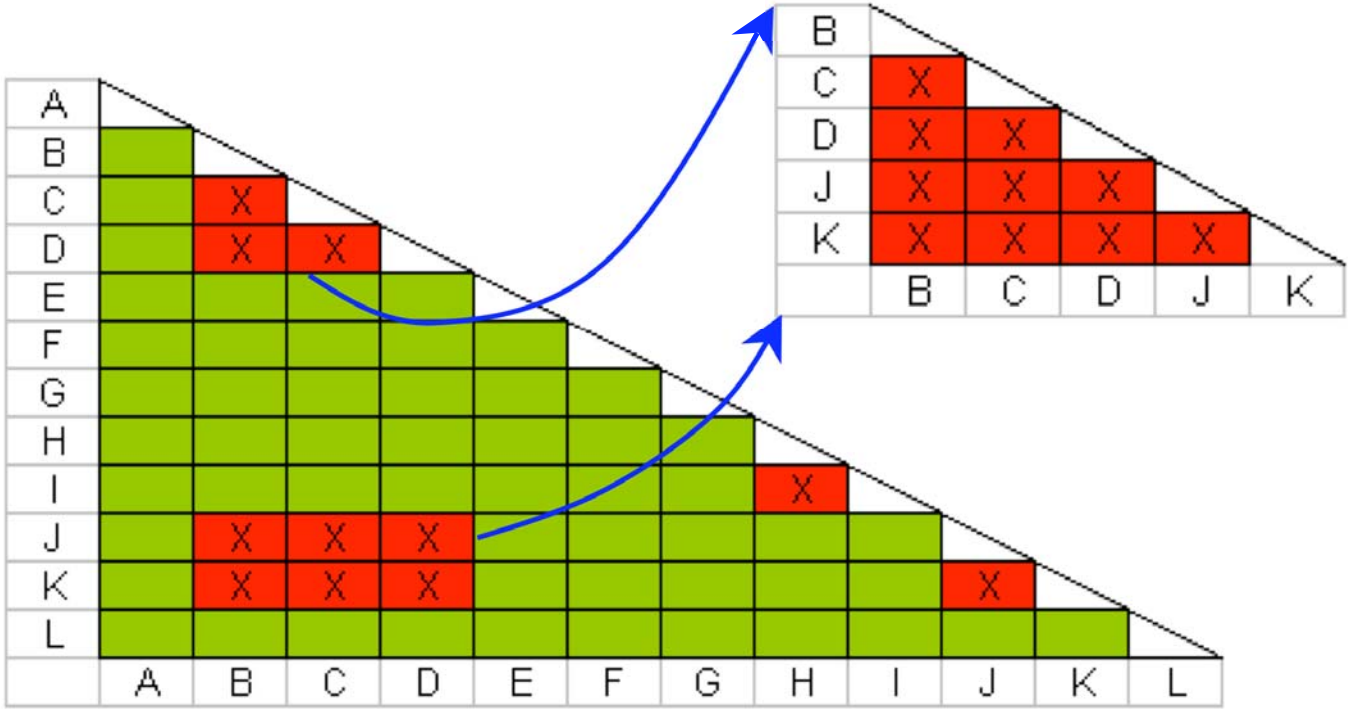


# Liners

| *(Sanders et al. 2004) Liner Pair | | Material Composition* | Fabric Backing? | Sample Thickness (mm) | Sanders Thickness (mm) | Shear Modulus (kPa) | Approximate Stiffness | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | mean | st dev |
| Alps ELDT 6mm | B | silicone gel | yes | 5.9 | 5.6 | 23.28 | 0.2929 | 0.0062 |
| Alps Super Stretch | C | silicone gel | no | 6.5 | 6.12 | 21.19 | 0.3074 | 0.0033 |
| ESP Aegis Ultimate | D | silicone gel | yes | 5.4 | 5.1 | 43.99 | 0.3703 | 0.0183 |
| Alpha 9mm | J | silicone gel | yes | 9.3 | 9.42 | 26.49 | 0.3449 | 0.0033 |
| Siloliner | K | silicone gel | yes | 5.1 | 5.21 | 19.29 | 0.3291 | 0.0076 |
| Iceross Original 2-color | H | silicone elastomer | no | 2.1 | 2.27 | 125.92 | 2.5449 | 0.1946 |
| Iceross Original Clear | I | silicone elastomer | no | 3.3 | 3.36 | 124.54 | 2.5481 | 0.1288 |
| Alps Clearpro | A | silicon elastomer | no | 3.2 | 2.06 | 90.54 | 1.7906 | 0.0324 |
| ESP Streamline | E | silicone elastomer | no | 2.0 | 2.19 | 175.2 | 2.0452 | 0.1244 |
| Iceross Dermo 6mm | G | gel silicone | yes | 6.1 | 5.81 | 52.86 | 1.0388 | 0.0355 |
| Profile Urethane | L | urethane | no | 6.8 | 6.29 | 82.73 | 1.2032 | 0.0312 |
| Iceross Comfort Plus | F | silicone elastomer | yes | 6.0 | 5.89 | 41.55 | 0.6084 | 0.0148 |

- Mak et al. 1994: soft tissue measurement on the lower limb yielded elastic modulus results 21 to 195 kPa.

# More on Liner Differentiation




X p-value > 0.05

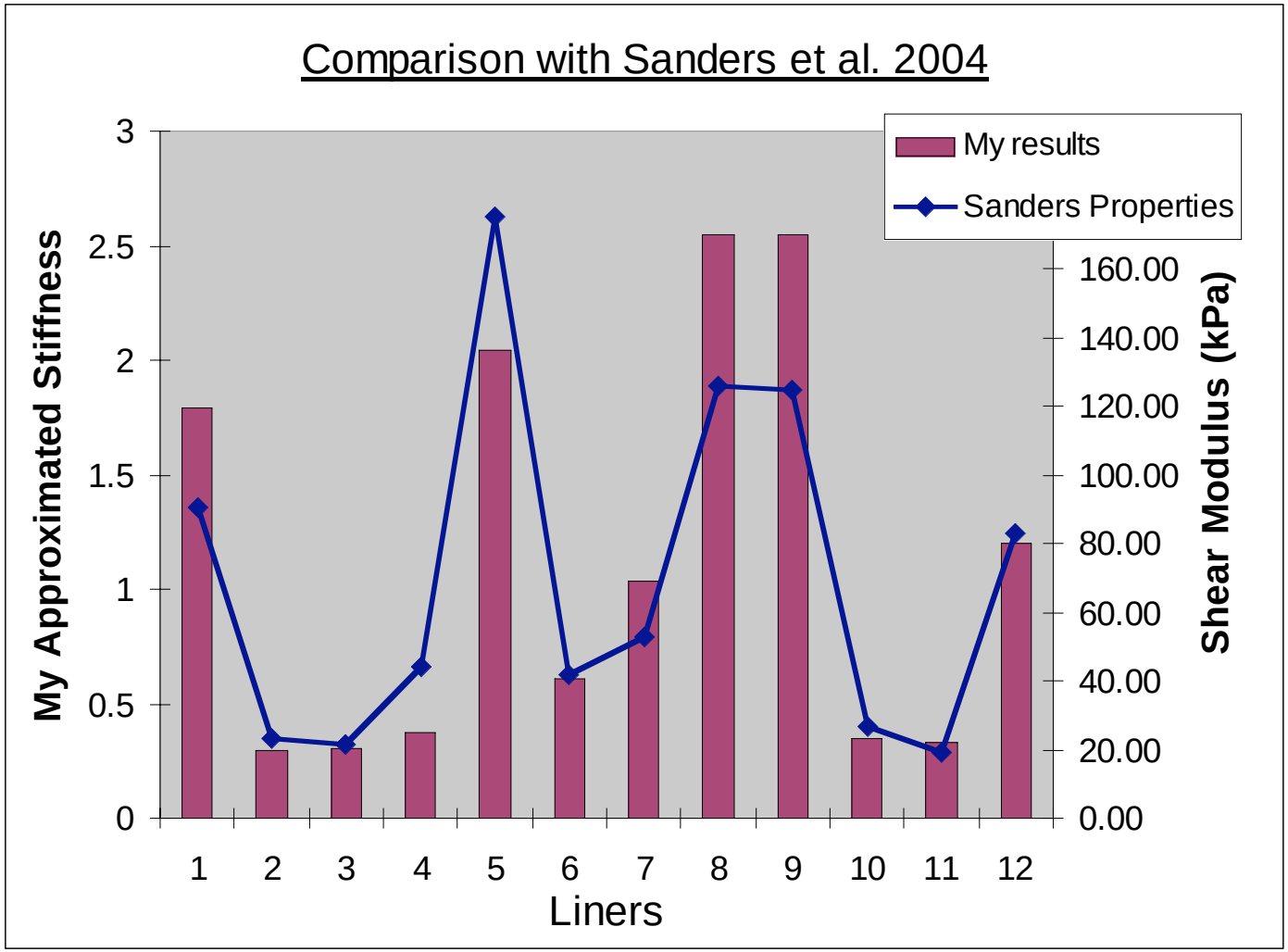
p-value < 0.05

- Liners BCDJK are the only silicone gels
- Liners H & I: Sanders et al. report only 1% difference in shear modulus properties

# Liner Limitation

| New Liner | Older Liner | % Difference in Approximated Stiffness |
|---|---|---|
| ESP Aegis Ultimate (new) | ESP AEGIS Z (old) | **3.14** |
| Iceross Dermo 6mm (new cut) | Iceross Dermo 6mm (old) | **31.79** |
| Iceross Original Clear 2mm (new) | Iceross Original Clear 2mm (old) | **17.47** |
| TEC (OttoBock) Urethane (new) | TEC Urethane (old) | **9.22** |

# Results: Relationship between device output and known properties?

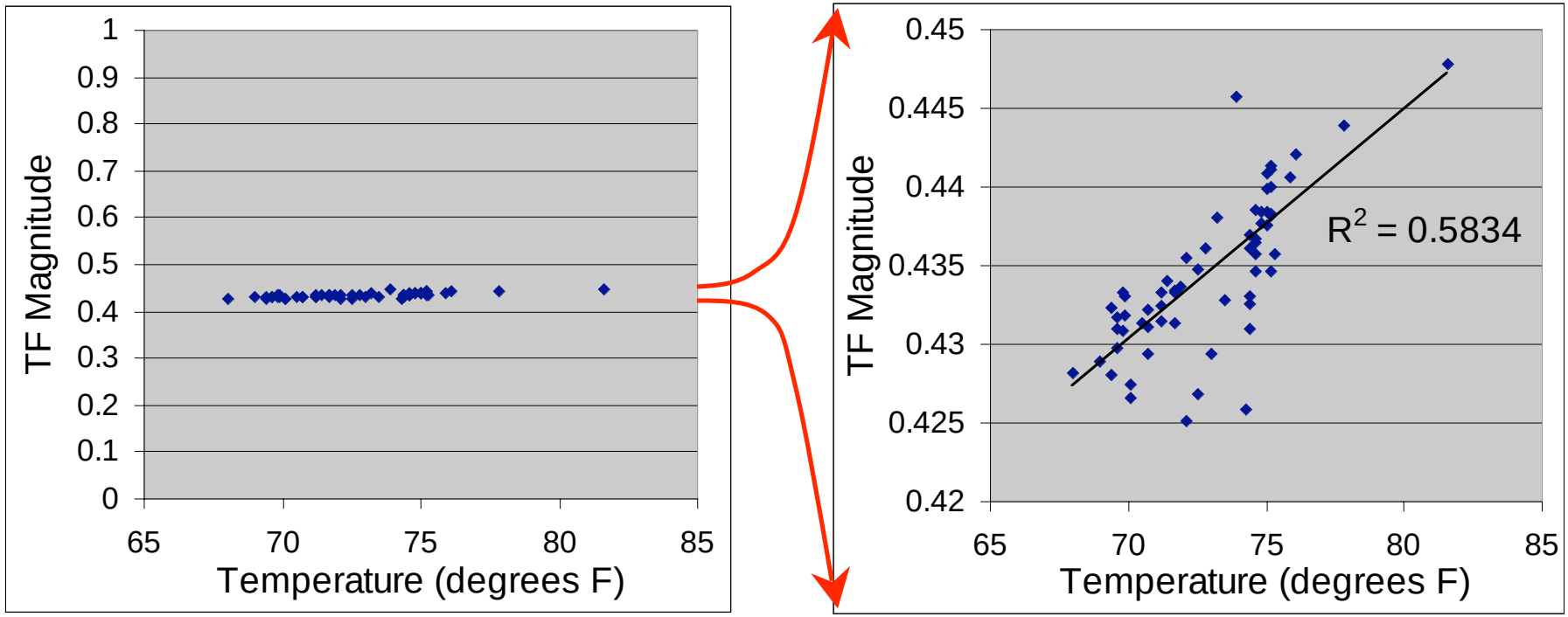


# Methods: Ambient Conditions

- Unloaded tests
- Range of ambient temperature and humidity conditions
  - Not actively manipulated
  - Temp: 68°F to 81.6°F
  - Humidity: 25% to 72.5%


(EXTECH Instruments)

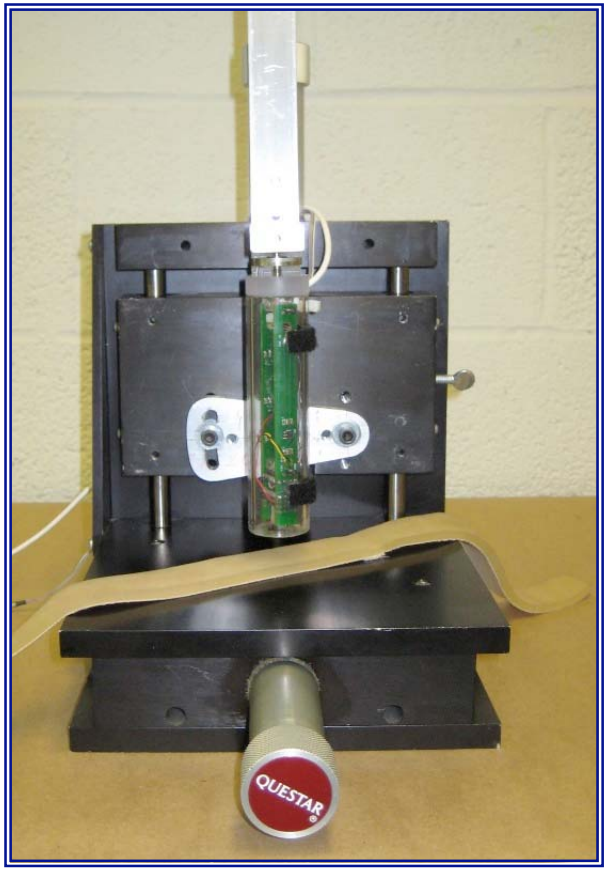
# Results: Ambient Conditions

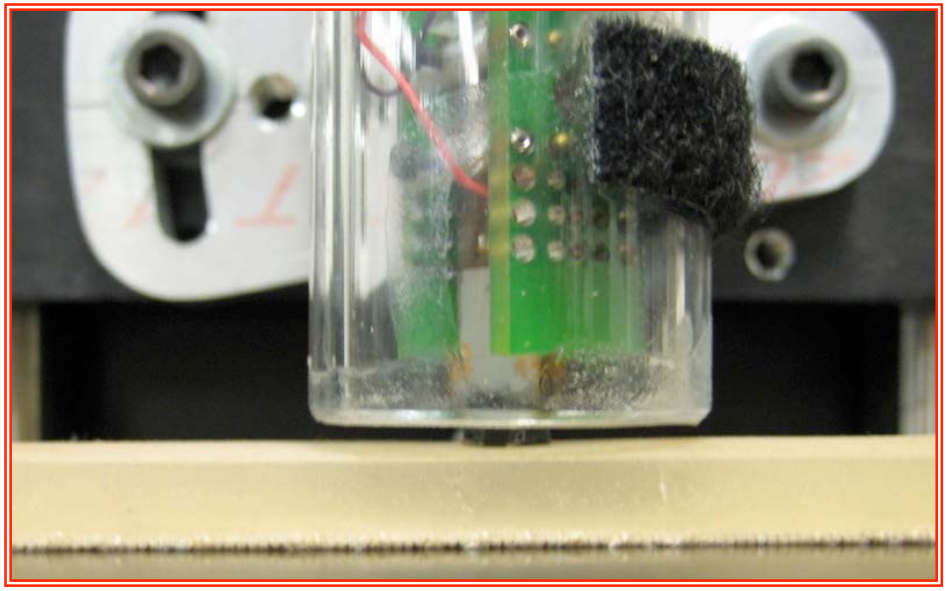



- CV = 1.2%

# Methods: Application Force

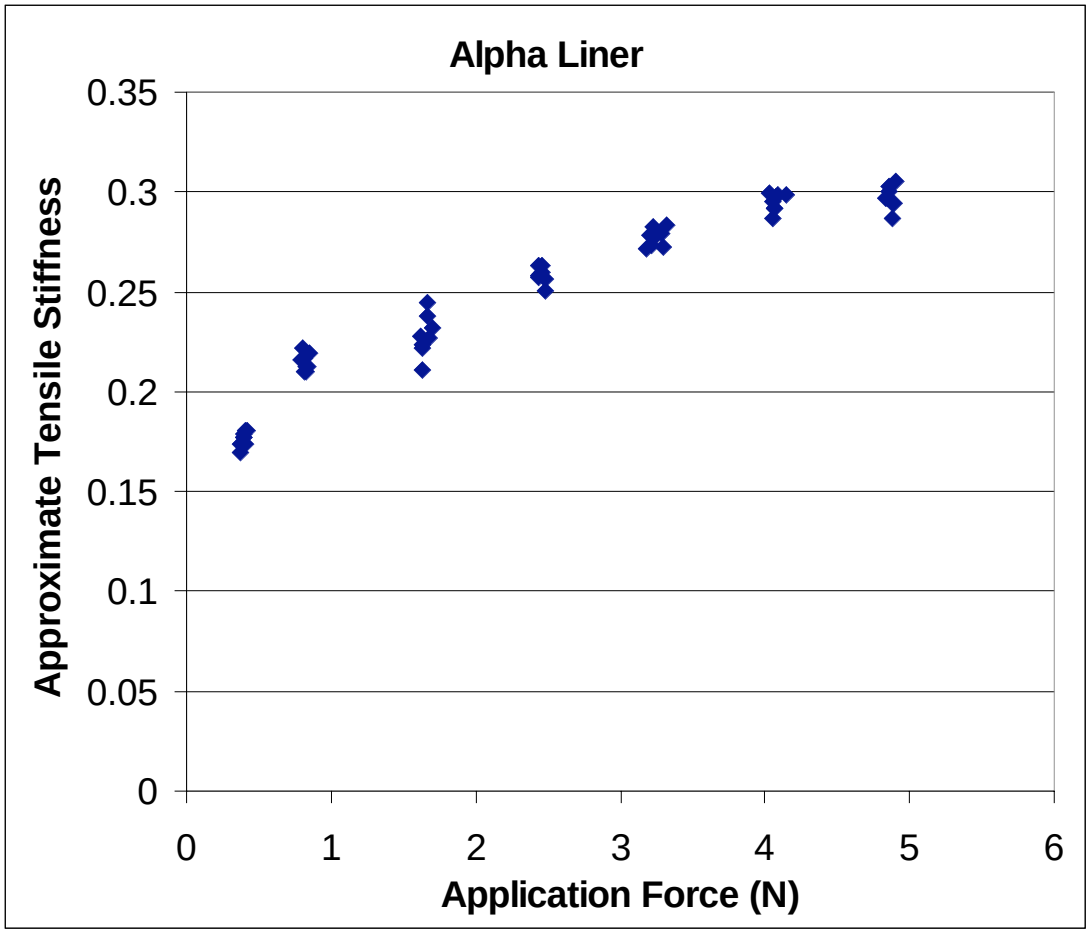
- Loaded tests
- Range of application forces:
  - Eight levels between 0.0 to 5.0 N
- Effect of force compared for different material and frequency conditions
- 8 repetitions per combo of conditions



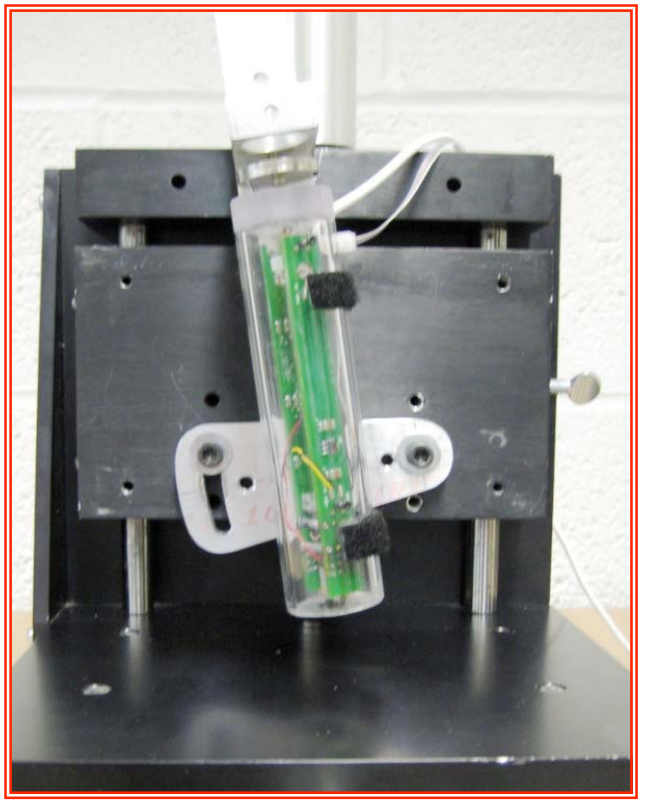
# Results: Application Force

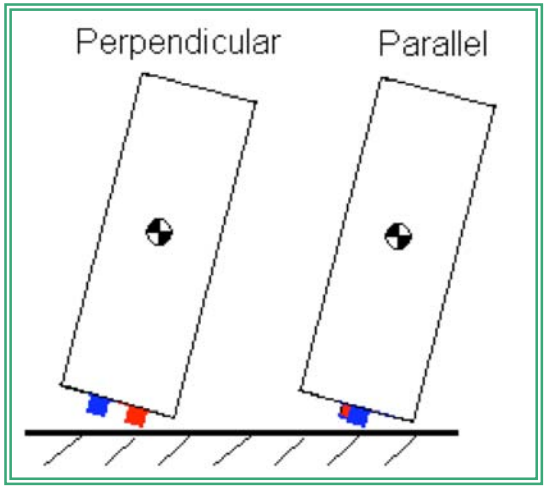
- Clear sensitivity to force of application
- Conclusion:
  - Usage protocol should include precise control of force



# Methods: Approach Angle

- Loaded Tests
- Range of Angles: 0, 2, 4, 6, 8°
- 2 orientations:
  - Feet parallel to rotation axis
  - Feet perpendicular
- Effect of angle compared for different material and force conditions
- 8 repetitions per scenario





# Results: Approach Angle